IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

MERCK & CO., INC., and MSD TECHNOLOGY, L.P. Plaintiffs,)	05	CV 05 Civ.	3699
CANADA DRUGS.COM PARTNERSHIP and KRIS THORKELSON, d/b/a CANADADRUGS.COM Defendants.))))			GEIVE PR 1 1 2005
COM	IPLAII	<u> YT</u>	U.S.)	D.C. S.D. N.Y. ASHIERS

Plaintiffs, Merck & Co., Inc. ("Merck") and MSD Technology, L.P. ("MSD"), by their undersigned attorneys, for their complaint against defendants Canada Drugs.com

Partnership and Kris Thorkelson, d/b/a canadadrugs.com ("canadadrugs.com" or "Defendants"), respectfully allege with knowledge of their own actions and on information and belief as to actions of others as follows:

- 1. This action is by Plaintiffs against canadadrugs.com for:
- (a) infringement of United States Patent No. 4,444,784 ("the '784 patent") under 35 U.S.C. § 271;
 - (b) trademark infringement under 15 U.S.C. § 1114(1);
- (c) unfair competition pursuant to § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a);
- (d) trademark dilution under the Federal Trademark Dilution Act, 15 U.S.C. § 1125(c);

- (e) trademark infringement and unfair competition in violation of the common law of New York and §§ 360-1 and 360-0 of the New York General Business Law;
- (f) injury to Merck's business reputation and dilution of the distinctive quality of Merck's trademarks in violation of § 360-1 of the New York General Business Law; and
- (g) unlawful deceptive acts and practices in violation of New York General Business Law §§ 349-350.

The Parties

- Merck is a corporation organized and existing under the laws of the State of New Jersey. Merck's headquarters are located at One Merck Drive, Whitehouse Station, New Jersey 08889.
- 3. MSD Technology L.P. is a limited partnership organized and existing under the laws of Delaware, with an address c/o Merck Sharp & Dohme Chibret A.G., 96 Pitts Bay Road, Pembroke HM 08 Bermuda.
- 4. Canada Drugs.com is a Canadian partnership having an address at 24

 Terracon Place, Winnipeg, Manitoba, Canada R2J 4G7. Kris Thorkelson is an individual having an address at 275 Vineland Crescent, Winnipeg, Manitoba, Canada R3Y 1T8. Canadadrugs.com does not have a place of business or employees located in the state of New York.
- 5. Canadadrugs.com: (a) controls, hosts and operates a website located at www.canadadrugs.com.com and uses that website to commit the tortious and wrongful activities described herein; and (b) is the owner of the Internet domain name canadadrugs.com, and uses that domain name to host the aforementioned website where Defendants advertise, promote, offer for sale and sell prescription drug products including those identified as "Zocor" and

"Generic Zocor" products in this judicial district and throughout New York and elsewhere in the United States.

Jurisdiction and Venue

- 6. This Court has subject matter jurisdiction over Count I in this action, pursuant to 28 U.S.C. § 1338(a); over Counts II through V in this action, pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1338(a); and over Counts VI through VIII in this action, pursuant to 28 U.S.C. §§ 1367 and 1338(b), and the doctrines of pendant and supplemental jurisdiction.
- 7. Canadadrugs.com has committed tortious and wrongful acts of patent and trademark infringement and dilution, unfair competition and acts in violation of the common law and state statutory laws by advertising, promoting, selling and offering to sell in the state of New York and elsewhere in the United States, certain prescription drug products, including those identified as "Generic Zocor" products.
- 8. Defendants have transacted and do transact business in the State of New York, by advertising, promotion, sales and offers to sell prescription drug products, including those identified in paragraph 7.
- 9. This Court has personal jurisdiction over Defendants based on the aforementioned activities in this judicial district.
- 10. Venue is proper in this District pursuant to the provisions of 28 U.S.C. §§ 1391(d) and 1400.

Merck's Patent

11. The '784 patent, entitled "Antihypercholesterolemic Compounds", was duly and legally issued to Merck on April 24, 1984 and was thereafter assigned to MSD, which is its current owner. Merck is the licensee of the '784 patent (copy attached at Tab A).

Merck's ZOCOR® (Simvastatin) Product and Trademarks

- 12. Merck, one of the world's leading pharmaceutical companies, is a global research-driven company that discovers, develops, manufactures and markets throughout the world a broad range of human health products. Merck invests billions of dollars in the research and development of its broad portfolio of highly-innovative prescription drugs.
- industry-leading products, including Merck's extremely successful prescription drug product ZOCOR®, which is used to treat patients who have or are at risk of coronary heart disease and/or have elevated cholesterol levels. The active ingredient in the ZOCOR® product is simvastatin. ZOCOR® brand simvastatin is used to reduce the amount of cholesterol and certain fatty substances in the blood.
- 14. Merck holds the approved U.S. Food and Drug Administration ("FDA")

 New Drug Application for its simvastatin product. There are no generic simvastatin products approved by the FDA for sale in the United States. Thus, Plaintiffs are the sole and exclusive entities authorized under the U.S. patent laws and the U.S. regulatory laws embodied in Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., to sell simvastatin product in the United States.
- 15. Merck's ZOCOR® brand simvastatin product has been continuously marketed and sold in the United States under Merck's ZOCOR® trademarks since at least November of 1986. Merck's ZOCOR® product is one of the most frequently prescribed medications in the United States. U.S. sales of the ZOCOR® product in 2004 totaled \$3.61 billion. Sales to customers in the State of New York in 2004 totaled approximately \$228.3 million.
- 16. Merck owns two United States trademark registrations for its ZOCOR® trademark for a pharmaceutical preparation for use as an antihypercholesterolemic agent. U.S.

trademark registration no. 1,457,984 for the word mark ZOCOR® issued on September 22, 1987. U.S. trademark registration 1,749,211 for the trademark ZOCOR (& Design)® issued on January 26, 1993. Both of these federal trademark registrations are valid, subsisting and incontestable under 15 USC § 1065. Copies of information from the U.S. Patent and Trademark Office website concerning Merck's United States ZOCOR® registrations are attached as Tab B. The ZOCOR® trademark is also registered in many different countries around the world.

The ZOCOR® and ZOCOR (& Design)® trademarks (hereinafter "the ZOCOR® trademark") are extremely well-known, famous and distinctive in the United States and in many countries of the world as designating the product originating with, sponsored by and associated with Merck. The ZOCOR® trademarks are extremely valuable assets that have acquired substantial goodwill.

Defendants' Illegal Activities

- 18. Canadadrugs.com offers for sale and sells prescription drugs to consumers over the Internet, including so called "Generic Zocor" products that are not authorized by Plaintiffs.
- 19. Canadadrugs.com's website is directed to customers outside of Canada, including, in particular, the United States. All advertised product prices are quoted in United States dollars and savings on medication costs between 25% and 75% are touted on the website. The stated savings represent a comparison of canadadrugs.com's prices with the price a consumer would expect to pay in the United States. An explanation of why some drugs have different names in Canada features the different brand names that are used in Canada and the U.S. for particular drugs.

- 20. Defendants' efforts to conduct business in the United States and to obtain a U.S. customer base have been successful. As many as 69% of the visitors to canadadrugs.com's website have been located in the United States at certain times, and canadadrugs.com has acknowledged that it fills around 3000 prescriptions per day, and has filled over 1 million prescriptions overall. Canadadrugs.com's website touts the facts that it has been endorsed or approved by the States of Wisconsin, New Hampshire, North Dakota and Minnesota, and that its CEO has received accredidation as a Licensed U.S. Pharmacist.
- 21. Canadadrugs.com's website is interactive and permits on-line interaction with prospective customers and customers, including on-line orders for the prescription drug products offered for sale. The website purports to operate as a local pharmacy would, providing service and assistance to its customers at their own location. New patients are required to fill out a patient order form which calls for medical information, address information and physician name and phone number, thereby facilitating contact by canadadrugs.com with the patient's local physician. The website offers receipts that can be submitted to the customer's insurance company for reimbursement.
- 22. Defendants' website lists names of the drugs offered, including "Zocor", which is listed on the site as one of the "most popular prescription drugs". When consumers "click" on the abovementioned listing of Zocor, or when they type "ZOCOR" into the "Search (Find Your Medication)" feature available on the home page and throughout the site, consumers are linked to a page that offers "Zocor" and "Generic Zocor" products in five dosage levels (5, 10, 20, 40 and 80 mg). The website invites the customer to purchase these "Zocor" and "Generic Zocor" products by clicking to indicate the desired dosage level and quantity, which leads to links where information is taken and processed, resulting in a sale. (A copy of the home page

and selected pages from Defendants' website are attached at Tab C). The medication is shipped directly to the consumer.

- 23. Defendants offer to sell and sell their "Generic Zocor" products in the United States and in this District at a variety of prices, depending on dosage level and quantity. As alleged above, all prices for this and other products offered for sale on Defendants' website are quoted in U.S. currency.
- 24. Defendants receive payment for the products they sell through their website to customers in the United States by transmittal from customers' credit card companies, which companies are located in the United States. Thus, these United States based companies hold funds for the benefit of Defendants.
- 25. The so-called "Generic Zocor" products sold on Defendants' website and delivered by Defendants to purchasers in New York and other states in the United States are not authorized or approved by Plaintiffs.
- 26. Defendants' use of the ZOCOR® trademark for the so-called "Generic Zocor" products is unauthorized by Merck and is used by Defendants to compete directly and unfairly with authorized products offered under the ZOCOR® trademark.
- 27. Defendants offer to sell, sell and ship to purchasers in New York and elsewhere in the United States, simvastatin products that are not authorized by law for sale in the United States, including the activities of Defendants alleged herein.

COUNT I INFRINGEMENT OF THE '784 PATENT (35 U.S.C. § 271)

28. Plaintiffs repeat and reallege paragraphs 1 through 27 above as if fully set forth herein.

- 29. Defendants' sales and/or offers for sale of simvastatin products in New York and elsewhere in the United States are without license or permission from Plaintiffs, and infringe the '784 patent under 35 U.S.C. § 271.
- 30. Plaintiffs have been and will continue to be irreparably harmed if Defendants are not enjoined from infringement of the '784 patent.
- 31. Defendants have had notice that certain of their products are covered by the '784 patent and have continued to willfully and deliberately infringe that patent.
- 32. The actions of Defendants have been "exceptional" within the meaning of 35 U.S.C. § 285.

COUNT II TRADEMARK INFRINGEMENT (15 U.S.C. § 1114(1))

- 33. Merck repeats and realleges paragraphs 1 through 32 above as if fully set forth herein.
- 34. Canadadrugs.com's activities in commerce in connection with the sale of its "Generic Zocor" products, as described above, are likely to cause confusion, mistake, or deception as to the source or sponsorship of such products and/or their affiliation with Merck, causing harm to Merck's reputation and goodwill. Purchasers and potential purchasers are likely to believe in error that such products are of the same quality and efficacy as Merck's products and/or that such products originate from, are approved by or are distributed by or under the authorization or sponsorship of Merck.
- 35. Canadadrugs.com's activities in commerce as alleged herein have resulted in actual confusion.

- 36. The use of the ZOCOR® trademark by canadadrugs.com described herein, which activities are without license or permission from Merck, constitutes infringement in violation of the Lanham Act, including section 32(1), 15 U.S.C. § 1114(1).
- 37. The activities complained of herein constitute willful and intentional infringement of the ZOCOR® trademark.
- 38. The conduct complained of herein has caused and will continue to cause substantial irreparable damage and injury to Merck for which there is no adequate remedy in law.

COUNT III UNFAIR COMPETITION AND FALSE DESIGNATION OF ORIGIN (15 U.S.C. § 1125(a))

- 39. Merck repeats and realleges paragraphs 1 through 38 above as if fully set forth herein.
- 40. Canadadrugs.com's use of the ZOCOR® trademark as described above, which is without license or permission from Merck, violates § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Canadadrugs.com has used a false designation of origin, a false or misleading description and representation of fact which is likely to cause confusion, mistake, and to deceive the public into believing that there is an affiliation, connection or association of canadadrugs.com with Merck, and/or that the so-called "Generic Zocor" products originate with, or are sponsored, licensed, approved or somehow sanctioned by or affiliated with Merck.
 - 41. The activities complained of herein are willful and intentional.
- 42. The conduct complained of herein has caused and will continue to cause substantial irreparable damage and injury to Merck for which there is no adequate remedy in law.

COUNT IV UNFAIR COMPETITION (15 U.S.C. § 1125(a)

- 43. Merck repeats and realleges paragraphs 1 through 42 as if fully set forth herein.
- 44. In the United States, ZOCOR patients who have purchased their medication in pharmacies located in this country are aware that there is no available FDA approved generic substitute for Merck's ZOCOR product, that the only available FDA approved simvastatin product in the United States is ZOCOR brand simvastatin, and that this product originates from or is sponsored and approved by a single source of origin, namely Merck. Thus, these patients understand that only Merck's ZOCOR brand simvastatin product can be lawfully sold in the United States.
- 45. Defendants' aforementioned activities violate § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Defendants have used in commercial advertising and promotions, words and false or misleading descriptions or representation of facts concerning the nature, qualities or characteristics of their goods or commercial activities and/or those of another person, i.e. Merck, and which also are likely to cause confusion, to cause mistake or to deceive the aforementioned United States ZOCOR patients. By such activities of Defendants, U.S. patients will be lead to believe that Defendants' generic simvastatin products are either legally authorized by the FDA for sale in the United States, or that such products originate with, or are sponsored, licensed, approved or somehow sanctioned by or affiliated with Merck, neither of which is in fact the case.
- 46. The activities of Defendants complained of herein are willful and intentional.

47. The conduct of Defendants complained of herein has caused and will continue to cause substantial irreparable damage and injury to Merck for which there is no adequate remedy at law.

COUNT V TRADEMARK DILUTION (15 U.S.C. § 1125(c))

- 48. Merck repeats and realleges paragraphs 1 through 47 above as if fully set forth herein.
- 49. The ZOCOR® trademark is strong and inherently distinctive. The mark has become famous as a result, *inter alia*, of Merck's long, extensive and continuously exclusive use of the mark, and Merck's extensive sales, advertising and promotion throughout the United States of products bearing the mark. As a result, the ZOCOR® trademark is favorably recognized by consumers and those in the trade as identifying the products of Merck. The unlawful acts of canadadrugs.com alleged herein were commenced and occurred at a time after Merck's mark became famous.
- 50. Canadadrugs.com's use of the ZOCOR® trademark in connection with the sale of its "Generic Zocor" products, which is without license or permission from Merck, has caused irreparable dilution of the distinctive quality of the ZOCOR® trademark in violation of 15 U.S.C. § 1125(c)(1), causing irreparable injury to Merck.
- 51. Through its activities alleged above, canadadrugs.com willfully intended to trade on Merck's reputation and to cause dilution of the ZOCOR® trademark.
- 52. The conduct complained of herein has caused and will continue to cause substantial irreparable damage and injury to Merck for which there is no adequate remedy in law.

COUNT VI TRADEMARK INFRINGEMENT AND UNFAIR COMPETITION (N.Y. General Business Law §§ 360-1, 360-0)

- 53. Merck repeats and realleges paragraphs 1 through 52 above as if fully set forth herein.
- 54. The acts of canadadrugs.com as described above, which are without license or permission from Merck, constitute trademark infringement and unfair competition in violation of Merck's rights under the common law of the State of New York and N.Y. General Business Law §§ 360-1, 360-0.
- 55. Merck has sustained and will continue to sustain irreparable injury as a result of the aforesaid illegal commercial activities, for which there is no adequate remedy at law.

COUNT VII DILUTION (N.Y. General Business Law § 360-1)

- 56. Merck repeats and realleges paragraphs 1 through 55 above as if fully set forth herein.
- 57. The acts of canadadrugs.com as described above, which are without license or permission from Merck, are likely to dilute and detract from the distinctiveness of the ZOCOR® trademark, with consequent damage to Merck and the business and goodwill symbolized by said trademark, in violation of the New York Anti-Dilution Statute, N.Y. Gen. Bus. Law § 360-1.
- 58. Merck has sustained and will continue to sustain irreparable injury as a result of the aforesaid illegal commercial activities, for which there is no adequate remedy at law.

COUNT VIII DECEPTIVE ACTS AND PRACTICES (N.Y. General Business Law § 349-350)

- 59. Merck repeats and realleges paragraphs 1 through 58 above as if fully set forth herein.
- 60. Canadadrugs.com's activities as described above, which are without license or permission from Merck, constitute deceptive acts and practices in violation of N.Y. Gen. Business Law §§ 349-350.
- 61. Merck has sustained and will continue to sustain irreparable injury as a result of the aforesaid illegal commercial activities, for which there is no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

- A. A judgment that the '784 patent has been infringed by canadadrugs.com;
- B. A judgment pursuant to 35 U.S.C. § 283 preliminarily and permanently enjoining canadadrugs.com and its officers, agents, servants, employees and affiliates, and all others in active concert or participation with any of the foregoing, from further infringement of the '784 patent;
- C. A judgment finding that canadadrugs.com's patent infringement has been willful and deliberate and that this is an exceptional case, pursuant to 35 U.S.C. § 284 and § 285;
- D. A judgment awarding Plaintiffs damages caused by the infringing activities and awarding increased damages and prejudgment interest;
- E. A judgment awarding Plaintiffs their attorneys' fees, costs and expenses in this action;
- F. A judgment that canadadrugs.com has infringed and diluted Merck's trademark rights in the ZOCOR® trademark, and has engaged in unlawful, unfair competition

under the provisions of the Lanham Act, 15 U.S.C. § 1051, et seq., as amended, and under the common law, and that such actions have been willful and intentional;

- G. A judgment that canadadrugs.com, its officers, directors, agents, servants, employees, representatives, successors and assigns, and all those in active concert or participation with any of the foregoing who receive actual notice of the injunctive order, be enjoined, preliminarily and permanently from:
 - a. Using the ZOCOR® trademark, or any other mark or term confusingly similar to the ZOCOR® trademark, in connection with the marketing, sale, offering for sale, advertisement, or promotion of its so-called "Generic Zocor" products;
 - b. Committing any act intended or likely to cause the public to believe that Defendants or any generic simvastatin product that Defendants sell is legally approved for sale in the United States by the FDA, or is in any manner connected, affiliated, sponsored, approved, or associated with Merck, from otherwise competing unfairly with Plaintiffs; and from making any false or misleading descriptions or representations of fact about theirs or Merck's products.
- H. That canadadrugs.com be directed to file with this Court and serve on Plaintiffs within thirty (30) days after entry of the injunction, a report in writing, under oath, setting forth in detail the manner in which canadadrugs.com has complied with the injunction.
- I. That canadadrugs.com be directed to account for and pay over to Merck all gains, profits and advantages derived from its wrongful acts pursuant to 15 U.S.C. § 1117(a).

- J. That Merck be awarded compensatory damages in an amount to be proven at trial, pursuant to 15 U.S.C. § 1117.
 - K. That Merck be awarded treble damages pursuant to 15 U.S.C. § 1117.
- L. That Merck be awarded costs, disbursements and attorney's fees pursuant to 15 U.S.C. § 1117.
- M. A judgment that canadadrugs.com has engaged in trademark infringement and unfair competition under New York General Business Law §§ 360-1, 360-0 and under New York common law.
- N. A judgment that canadadrugs.com has caused injury to Merck's business reputation and dilution of the distinctive quality of Merck's trademarks in violation of § 360-1 of the New York General Business Law.
- O. A judgment that canadadrugs.com has engaged in unlawful deceptive acts and practices in violation of New York General Business Law §§ 349-50.
- P. An order pursuant to Fed. R. Civ. Pro. 64 in favor of Plaintiffs attaching any assets of canadadrugs.com within the jurisdiction of this Court.

Q. That Plaintiffs be awarded such other and further relief as this Court may deem just and proper.

FITZPATRICK, CELLA, HARPER & SCINTO

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Dated: New York, New York April 11, 2005